US ERA ARCHIVE DOCUMENT

U.S. EPA **Endocrine Disruptor** Screening Program (EDSP) Update for the PPDC

April 22, 2009

EPA's Statutory Authority

Food Quality Protection Act (FQPA)

Requires EPA to: Develop a screening program using validated assays to identify pesticides that may have estrogenic effects in humans.

Authorizes EPA to include:

Other endocrine effects, as designated by the EPA Administrator (e.g., androgen and thyroid; endocrine effects in species other than humans).

Other non-pesticide chemicals that:

- Have "an effect cumulative to that of a pesticide," and
- To which a substantial human population may be exposed.

Safe Drinking Water Act (SDWA) Amendments

Allows EPA to require testing of chemical substances found in sources of drinking water, if a substantial human population may be exposed.

EDSP Activities

- Assay Validation -- Developing and validating assays (Tier 1 screening & Tier 2 testing)
- 2. Priority Setting -- Selecting chemicals to be screened
- **3. Procedures** -- Developing procedures for requiring testing

Assay Validation

Tier I Assays*

ER binding peer review to be completed this month

Completed:

Uterotrophic

Hershberger

ER Transcriptional Activation

Female Pubertal

Male Pubertal

AR Binding

Aromatase

Amphibian Metamorphosis

Fish Screen

Steroidogenesis

Tier II Assays

- Completed: Mammalian 2-generation
- To be Completed in 2010:
 Avian 2-generation
 Amphibian Growth/Reproduction
 Fish 2-generation
 Mysid 2-generation

^{*} FIFRA SAP reviewed the proposed EDSP Tier 1 Battery on March 25-27, 2008 (SAP Report, June 11, 2008)

Priority Setting and Procedures

The following Federal Register notices were issued April 15:

- The final list of initial pesticide active ingredients and pesticide inert ingredients to be screened under FFDCA
- Policies and procedures for initial screening under EDSP
- Information Collection Request (ICR), as required under the Paper Reduction Act, for 30-days of public comment

Agency responses to public comments on the list and policies and procedures are available in the docket.

Next steps:

- Publish Federal Register notice announcing the Tier 1 Screening Battery (est. May 2009)
- Complete formal OMB review of ICR (est. mid June 2009)
- Issue first EDSP associated orders (est. July 2009)

More information: www.epa.gov/endo